MAY 26 2006

K060546

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter	Breas Medical AB
	Företagsvagen 1
	SE 435 33 Molnlycke
	Sweden
Contact Person	Karl- Johan Holm
	Quality Assurance and Regulatory Affairs Manager
	Phone: +46 31 868830
	Fax: +46 31 868810
Summary Date	February 13, 2006
Name of Device	Breas Vivo 30 System
Common Name	Bilevel system
Classification Name	Non- continuous ventilator (21 CFR 868.5895
Product Code	MNS
Predicate Device	ResMed VPAP II ST-A (K974417)

Device Description:

The Vivo 30 is a pressure-supported and pressure-controlled ventilator with a CPAP function intended for spontaneous breathing patients who require long-term support by mechanical ventilation during night and part of the day.
In the treatment of chronic respiratory failure, positive airway pressure ventilation is well established and common practice as a mean to assure sufficient gas exchange. There are a number of devices legally marketed in the United States for this application.

The Vivo 30 can be used in clinical settings (e.g., hospitals, sleep laboratories, sub-acute care institutions) and home environments. It must always be prescribed by a licensed physician.

It is not intended for life support applications or for transport of critical care patients.

The therapy delivered by the Breas Vivo 30 System can be either:

1) Pressure Controlled Ventilation (PCV) or
2) Pressure Support Ventilation (PSV) or
3) Constant Positive Airway Pressure (CPAP)

The Vivo 30 airflow is delivered via a single lumen outlet tube that may be connected to various non-invasive patient interfaces, such as nasal masks. To minimize CO_2 rebreathing, masks or other interfaces permitting a leak flow of at least 12 liters/minute at the output pressure setting of 4 cmH_20 are recommended.

The Vivo 30 has an auto-switching power supply that facilitates use in conjunction with international travel (100 – 240 VAC). It can also be used with an external 12.5/ 24 VDC power source when AC mains line voltage is not available.

The outer dimensions of the Vivo 30 housing are 7.2 × 8.9 × 8.9 inches, and the device weighs 7.3 pounds.

Intended Use:

The Breas Vivo 30 is designed for spontaneous breathing patients who require long-term support by mechanical ventilation during night and part of the day.

The Breas Vivo 30 shall only be used by patients with spontaneous breathing.

The Breas Vivo 30 is not intended for life support or life-sustaining applications or for transport of critical care patients.

The Breas Vivo 30 is intended for non-invasive use.

The Breas Vivo 30 is intended for treatment of adult (who weigh more than 30 kg) patients.

The Breas Vivo 30 is intended to be operated by qualified and trained personnel.

Comparison of Use and Technological Characteristics:

The Vivo 30 can be used in clinical settings (e.g., hospitals, sleep laboratories, sub-acute care institutions) and home environments. It must always be prescribed by a licensed physician.

It is not intended for life support applications or for transport of critical care patients.

As compared with the cited predicate device, the Breas Vivo 30 System has:

Same intended uses

Same environments of use

Similar design (microprocessor-controlled blower as air source)

Same technology (software based pressure-, flow- and time- regulation)

The differences that do exist are minimal and involve primarily user preference features. The Breas Vivo 30 System has additional display indicator and audible alarm features as well as lockout features (to provide clinicians with optional means to control the ability of patients to change pressure settings). These features are described in labeling for the device that includes an Operator Manual.

Summary of Performance Testing:

1. Non-clinical testing was conducted to verify that the Breas Vivo 30 System is capable of meeting its stated performance specifications and that all Risk Analysis issues have been appropriately addressed. The device passed all tests.

2. Comparative testing to predicate devices was performed. This bench- testing confirmed that the Breas Vivo 30 System is substantial equivalent with regards to Wave-form performance as well as Work of Breathing and Pressure Dynamic regulation.

3. Testing was conducted to demonstrate compliance with applicable requirements in the November 1993 draft "Reviewer Guidance for Premarket Notification Submissions" published by the FDA's Division of Cardiovascular, Respiratory,

and Neurological Devices and the July 1995 "Draft Reviewer Guidance for Ventilators". The testing included but was not limited to:

- Electrical Safety testing per IEC 601-1
- Safety and Essential Performance testing per ISO 10651-6
- Safety and Performance testing per ISO 17510-1
- Electromagnetic Compatibility testing (EMC testing)
- Mechanical Safety testing
- Environmental testing
- Functional testing
- Particle matter testing

The device passed all tests.

4. All device (the embedded software and the Calendar Analysis PC software) softwares was documented and tested in accordance with the FDA's May 11, 2005 "Guidance for the content of Premarket Submissions for Software Contained in Medical Devices". The device passed all tests.

5. Clinical studies were not required to support a substantial equivalence determination.

Conclusions:

The Breas Vivo 30 System meets its stated performance specifications and criteria outlined in the Reviewer Guidance publications referenced above. We conclude that the device is capable of operating safely in its intended environments and will be effective in fulfilling its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 26 2006

Mr. Karl-Johan Holm
Quality Assurance & Regulatory Affairs Mananger
Breas Medical AB
Företagsvagen 1
Molnlycke, Vastra Gotaland
SWEDEN `SE 435 33

Re: K060546
Trade/Device Name: Breas Vivo 30 System
Regulation Number: 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: MNS
Dated: February 22, 2006
Received: March 1, 2006

Dear Mr. Holm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

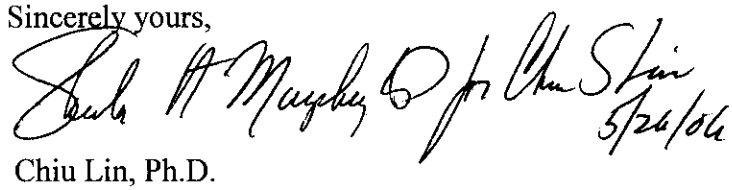
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K060546

Device Name: Breas Vivo 30 System

Indications For Use: The Breas Vivo 30 is designed for spontaneous breathing patients who require long-term support by mechanical ventilation during night and part of the day.

Prescription Use__X__ AND/OR Over-the-Counter Use____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[signature]

...ology, General Hospital,
...ol, Dental Devices

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